MAR 2 4 2000

DENTSPLY

# 510(k) SUMMARY

NAME & ADDRESS:

**DENTSPLY International**
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
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K000169

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: January 17, 2000

TRADE OR PROPRIETARY NAME:
NUPRO® T PROPHYLAXIS PASTE WITH FLUORIDE AND TRICLOSAN

CLASSIFICATION NAME: Oral cavity abrasive polishing agent 872.6030

PREDICATE DEVICES: NUPRO® T Prophylaxis Paste with Fluoride & Triclosan K983966

DEVICE DESCRIPTION: NUPRO® T PROPHYLAXIS PASTE WITH FLUORIDE AND TRICLOSAN is a unique blend of polishing and cleaning agents designed for professional application during standard dental practice hygiene procedures. The device contains fluoride, triclosan, an abrasive, a sweetener, water, flavoring, color, thickeners, and preservatives.

INTENDED USE: NUPRO® T PROPHYLAXIS PASTE WITH FLUORIDE AND TRICLOSAN is to be used for: (1) Cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment; and (2) Professional cleaning and polishing of plastic oral appliances and prostheses, which have been removed from the mouth.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in NUPRO® T PROPHYLAXIS PASTE WITH FLUORIDE AND TRICLOSAN have been used in the predicate device or been found to be safe for dental use.

Studies concluded that triclosan is non-carcinogenic, non-mutagenic, is a non-irritant and a non-sensitizer.

We believe that the performance data provided and the fact that the device is unchanged from K983966 support the safety and effectiveness of NUPRO® T PROPHYLAXIS PASTE WITH FLUORIDE AND TRICLOSAN for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2000

Mr. P. Jeffery Lehn
Director, Corporate Compliance
and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K000169
Trade Name: Nupro® T Prophylaxis Paste with Fluoride and Triclosan
Regulatory Class: I
Product Code: EJR
Dated: January 17, 2000
Received: January 20, 2000

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K000169

DEVICE NAME: NUPRO® T PROPHYLAXIS PASTE WITH FLUORIDE AND TRICLOSAN

INDICATIONS FOR USE:

**Addition of New Indication**:

- To be used for professional cleaning and polishing of plastic oral appliances and prostheses, which have been removed from the mouth.

**Current Indication, K983966**:

- To be used for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K000169